

**DEVICE AND METHOD OF REDUCING FRICTION AND DISPLACEMENT OF
OSTOMY APPLIANCES**

Priority

[1] This application claims priority from United States provisional patent
5 application No. 60/462,074, filed April 10, 2003, which is incorporated herein by
reference.

Field of the Invention

[2] The present invention relates to a cover for ostomy appliances, and in
particular to a low-friction cover that reduces forces applied to the ostomy appliance by
10 clothing and intimate contact.

Background

[3] Ostomy appliances are widely used post surgical appliances for patients
that have undergone a surgical procedure resulting in intestinal waste elimination
through a stoma in an abdominal wall. These appliances and their use are described in
15 U.S. Patent No. 4,211,224, for FILTER VENTING DEVICES FOR OSTOMY
APPLIANCES issued July 8, 1980, and U.S. Patent No. 5,356,399, for OSTOMY
APPLIANCE issued October 18, 1994, both of which are incorporated herein by
reference.

[4] The term "ostomy" covers all types of surgical procedures wherein a
20 passageway is formed through the skin and a portion of the intestine connected thereto.
When a portion of the large intestine or colon is connected to the stoma or passageway,
the surgical procedure is referred to as a "colostomy". When the small intestine is
involved, the surgical procedure is known as a "ileostomy". Both types of procedures
require an ostomy appliance, such as a cap or bag which is affixed or worn on the body
25 and is in communication with the stoma. The cap generally functions as a protective
cover and limits waste material exiting from the stoma. The bag additionally provides for
collection of waste products. A wide variety of ostomy caps and bags, and methods for
attaching them to the body have been previously devised. For purposes of describing

background and embodiments of the invention, embodiments are described with reference to an appliance used in conjunction with a colostomy.

[5] Colostomy appliances, particularly ostomy caps (sometimes known as stoma caps), are adhered to skin adjacent to the stoma and are generally worn
5 relatively unobtrusively beneath the wearer's clothing. Most colostomy appliances are constructed of materials that do not breath so they can perform their designed function of retaining waste products. However, the non-breathable materials used in colostomy appliances generally frictionally resist movement of the wearer's clothing over them. Because of the friction, clothing chafes, rubs, and scuffs against the appliance,
10 sometimes resulting in folding, displacing, or disengaging the appliance from the stoma site. Any displacement or disengagement of the colostomy appliance can cause leakage, soiling, odor, and wearer embarrassment. Furthermore, the non-breathable nature of colostomy appliances causes moisture accumulation between a portion of the appliance and the wearer's skin. Additionally, the non-breathable materials can be
15 uncomfortable against an intimate partner's skin.

[6] In view of the foregoing, there is a need in the art for a new and improved apparatus and method for reducing friction between colostomy appliances and a wearer's clothing or an intimate partner. There is a further need for limiting moisture buildup between the colostomy appliance and the wearer's skin.

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Summary

[7] An embodiment of the present invention provides an ostomy appliance cover. The cover includes a first sheet of flexible material having at least one low coefficient of friction surface and dimensioned to cover a first portion of the ostomy appliance, and a second sheet of flexible material that is elastic and breathable,
25 dimensioned to cover a second portion of the ostomy appliance. The second sheet of material includes an expandable opening, which when expanded allows the ostomy appliance to pass through the opening without substantial distortion of the ostomy appliance, and when released substantially covers the colostomy appliance in cooperation with the first sheet of material.

[8] These and various other features as well as advantages of the present invention will be apparent from a reading of the following detailed description and a review of the associated drawings.

Brief Description of the Drawings

5 [9] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. Aspects of the invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like referenced numerals identify like elements,
10 and wherein:

[10] Figure 1 illustrates a side view of a colostomy appliance applied to a wearer's skin in an area of a stoma;

[11] Figure 2 illustrates a stoma-side plan view of an ostomy appliance cover, according to an embodiment of the invention;

15 [12] Figure 3 illustrate a cross-section side view of an ostomy appliance cover, according to an embodiment of the invention; and

[13] Figure 4 illustrates a side view of the colostomy appliance of FIG. 1 with a colostomy appliance cover fitted over the colostomy appliance, according to an embodiment of the invention.

Detailed Description

20 [14] In the following detailed description of exemplary embodiments of the invention, reference is made to the accompanying drawings, which form a part hereof. The detailed description and the drawings illustrate specific exemplary embodiments by which the invention may be practiced. These embodiments are described in sufficient
25 detail to enable those skilled in the art to practice the invention. It is understood that other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the present invention. The following detailed description is

therefore not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

[15] FIG. 1 is a side view of a colostomy appliance **20**, illustrated by a cap, applied to a wearer's skin **10** in an area of a stoma **12** of the human body. The colostomy appliance **26** may be round, rectangular, or any other shape known in the art suitable for performing the function of the colostomy appliance. The colostomy appliance **20** may be any type of appliance for fitting over the stoma **12**, such as the COLOPLAST® 5540, 5560 & 5700, and the CONVATEC® 22710. The appliance **20** includes an outer-surface portion **28** and a wearer's skin-side portion **29**.

[16] The skin-side portion **29** includes an adhesive portion **22** that surrounds an inlet **24** of the appliance **20**, and that is arranged for removable adhesive attachment to the wearer's skin **10** and for mating alignment with the wearer's stoma **12**. The appliance **20** further includes a chamber **26** for receiving gases and waste products discharged from the stoma **12**. The outer surface **28** of the colostomy appliance faces away from the wearer's skin **10** and will contact the wearer's clothing or a person in intimate contact with the wearer. The colostomy appliance **20**, including the outer surface portion **28** and the skin-side portion **29**, is typically made from non-breathable materials that frictionally resist movement of the wearer's clothing relative to the appliance. Furthermore, perspiration and moisture typically form in area **14** between the wearer's skin **10** and the skin-side portion **29** of the colostomy appliance **26**.

[17] FIGS. 2 and 3 illustrate a stoma-side plan view and a cross-section side view respectively of an ostomy appliance cover **40**, according to an embodiment of the invention. The cover **40** includes a sheet of material **44** having a low coefficient of friction surface **45**, and a sheet of elastic, breathable material **48**. The sheet of breathable material **48** includes an expandable opening **46** having a seam **47** around a peripheral portion of the opening providing reinforcement of the opening and additional elasticity.

[18] The sheet of material **44** having the low coefficient of friction surface **45** is configured for a close fit with the outer surface **28** of the appliance **20**. The low

coefficient of friction surface **45** is orientated facing away from the outer surface **28** and for contact with the wearer's clothes and persons in intimate contact with the wearer. The sheet of elastic, breathable material **48** is configured for a close fit with the skin-side surface of the cover **40**.

5 **[19]** The sheet of low coefficient of friction material **44** and the sheet of elastic, breathable material **48** each have an outer peripheral edge, and are coupled together at their respective outer peripheral edges by the seam **42** to cooperatively form the cover **40**. The seam **42** can be formed in manner known in the art, including stitching, gluing, or both. In an alternative embodiment, the cover **40** may be made from a single piece
10 of material arranged to cover the colostomy appliance **20**.

[20] The cover **40**, including sheets **44** and **48**, is optimally configured for a close fit with the appliance **20** to reduce movement of the cover with respect to the appliance **20** while still allowing for expansion of the appliance for gas and waste products. Additionally, sheets **44** and **48** are optimally configured to lay proximate to
15 the outer surface **28** and the skin-side surface **29** of the appliance **20** without wrinkles.

[21] The colostomy appliance cover **40** may be constructed of any materials suitable for its intended purpose known to those in the art, particularly materials that are lightweight, longwearing, and washable. The flexible material **44** having a low coefficient of friction surface **45** may be any flexible sheet or planar material with at least
20 one surface having a low coefficient of friction with respect to clothing or human skin. The low coefficient of friction surface **45** may be a surface of a material having a smooth, silky or satiny surface. Such a surface may include low-friction fibers, a combination of fibers resulting in a low-friction surface, or a material modified to have a low-friction surface. The flexible material may be a film, sheet, or woven material, and
25 may be natural, synthetic, organic, or inorganic. A low coefficient of friction surface **45** generally has a coefficient of friction of less than 0.3. The flexible material **44** may also be breathable.

[22] The sheet of elastic, breathable material **48** may be any elastic, breathable material known to those in the art, including fabric materials with a weave

that allows breathability, and materials perforated for breathability. The material **48** includes sufficient elasticity for the expandable opening **46** to be pulled over an outside diameter (not shown) of a colostomy appliance **10** without significantly distorting the appliance. The edge of the opening **46** can be surged with a flexible stitching to prevent
 5 unraveling while allowing the colostomy appliance cover **40** to be easily put on and removed. The colostomy appliance cover **40** may be constructed in a variety of colors and utilize a variety of decorative patterns.

[23] An example of an ostomy appliance cover was made to cover a round Coloplast model 5540 stoma cap cover having a 4.6-inch overall outside diameter, and
 10 an outside diameter around the adhesive portion **22** of 2.8 inches. A commonly available Lycra Spandex® material having at least one low coefficient of friction surface **45** was used for both the flexible material **44** and the sheet of elastic, breathable material **48**. The two sides are cut such that their outer peripheries, when sewn together by seam **42**, form an inner diameter (not shown) of approximately 4.8 inches.
 15 Generally, it has been found that the cover **40** functions well when between one-sixteenth and one-fourth-inch larger than the stoma appliance cover **20**, with one-eighth-inch being a preferred dimension. The opening **46** in the material **48** is cut for a finished diameter of approximately 2.4 inches; being slightly smaller than the 2.8-inch outside diameter of the adhesive portion **22** and providing a small, elastic gripping of the
 20 appliance cover **20** by the stoma cap cover **40** at the adhesive portion. The opening **46** is reinforced with stitching **47** in a zigzag pattern about the opening with an elastic thread at about 8-12 stitches per inch. The seam **42** is sewn in a straight pattern with an elastic thread at 8-12 stitches per inch. Typically, the two pieces of material are sewn together inside out, and then turned right side out to provide a finished edge and
 25 look.

[24] FIG. 4 is side view of the colostomy appliance **20** of FIG. 1 with the colostomy appliance cover **40** of FIGS. 2 and 3 fitted over the colostomy appliance **20**, according to an embodiment of the invention.

[25] The cover **40** may be applied to the appliance **20** either before or after the appliance **20** is adhered to a patient's skin **10**. For example, after the appliance **20** is adhered to the patient's skin **20** by the adhesive portion **22**, the expandable opening **46** is expanded by stretching and flattening with the wearer's fingers to a point where the opening **46** is substantially flat and approximately equal to, or larger than, an outside dimension of the appliance **20**. By way of further example using the embodiment of the invention constructed as described in conjunction with FIGS. 2 and 3 with the 4.6-inch diameter round appliance, the expandable opening **46** is expanded into a slit configuration having a length longer than 4.6 inches. The cover **40** is then pulled over the appliance **20** in a motion from the patient's feet toward the patient's head. Because of the elasticity in at least the material **48** comprising the opening **46**, the cover **40** with the expanded opening configuration easily fits over the appliance **20** without substantial distortion of the worn appliance. When released from the expanded opening configuration, the cover **40** substantially covers the cap **20**.

[26] Once the cover is applied, the elastic, breathable material **48** allows moisture to move away and helps to prevent friction, chafing, and irritation of skin **10** area around the stoma **12**. The low coefficient of friction surface **45** prevents the appliance **20** from folding or wadding up under the wearer's clothing, and keeps the appliance **20** lying close to the skin. One of the many advantage to this feature is that "wadding and folding" can lead to premature failure of the cap-sealing features. Additionally, it is much easier to wear close-fitting clothing without embarrassing bulges. In addition, the colostomy appliance cover also provides some protection of clothes and keeps an undergarment from soiling when minor leaks and failures occasionally occur. Furthermore, the colostomy appliance cover **40** promotes more comfortable intimate contact by helping to maintain adhesion to the wearer's skin, eliminating potential binding against a partner's skin, and providing a more attractive appearance than the non-breathable material from which an ostomy cap is typically manufactured.

[27] Additional advantages of the colostomy appliance cover **40** include being reusable and easy to maintain. It launders easily due to the material it is constructed

from, such as lycra spandex which dries quickly for reuse. A spare colostomy appliance cover **40** can be carried unobtrusively on one's person.

[28] Although the present invention has been described in considerable detail with reference to certain preferred embodiments, other embodiments are possible.

- 5 Therefore, the spirit or scope of the appended claims should not be limited to the description of the embodiments contained herein. It is intended that the invention resides in the claims hereinafter appended.